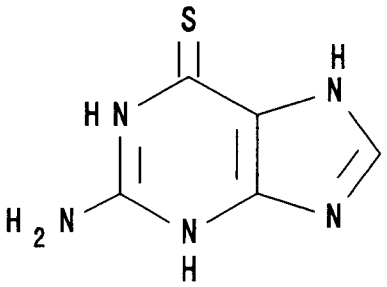
THIOGUANINE

NSC - 752

The following information applies to the investigational intravenous dosage form of thioguanine. For information regarding the commercially available dosage form (tablets), consult the package insert prepared by the Burroughs Wellcome Company.



Chemical Name: 6H-Purine-6-thione, 2-amino-1,7-dihydro-

Other Names: 6-Thioguanine, 6-TG, Tabloid®, Thioguanine (USAN)

CAS Registry Number: 154-42-7

Molecular Formula: $C_5H_5N_5S$ **M.W.:** 167.2

How Supplied: Sterile, 75 mg, vial: supplied as a lyophilized powder in 10 mL flint vials. Sufficient sodium hydroxide has been added to yield the sodium salt of thioguanine equivalent to 75 mg of thioguanine base.

Solution Preparation: 75 mg/vial (as thioguanine): When constituted with 5 mL of 0.9% Sodium Chloride Injection, USP, each milliliter of solution contains 15 mg of thioguanine and sodium hydroxide for adjustment to pH 11.0 to 12.0.

Storage: Store the intact vials at refrigeration temperature (2-8 °C).

Stability: Shelf-life surveillance of the intact vials is ongoing. The intact vials are stable for at least 4 years at refrigeration temperature (2-8 °C) and 3 years at room temperature (22-25 °C). The intact vials are stable for at least one year at elevated temperature (50 °C).

Constitution as recommended results in a solution which is stable for at least 24 hours under refrigeration (2-8 °C).

NOTE: Room temperature storage of constituted solutions may result in precipitate formation upon standing.

Further dilution in 500 mL of 5% Dextrose in 0.9% Sodium Chloride Injection, USP, results in a solution which is stable for at least 24 hours at room temperature or refrigeration temperature.

Admixture of 0.5 mEq of sodium bicarbonate per 75 mg of thioguanine to infusion solutions containing 1 mg/mL of thioguanine in either 5% Dextrose Injection, USP, or 0.9% Sodium Chloride Injection, USP, has been performed.

Addition of the sodium bicarbonate lowers the pH from about 11.5 to about 9.5. The admixture is physically and chemically stable for 8 hours both at room temperature and under refrigeration. Drug decomposition noted in this time interval was about 2 to 3% in the 0.9% Sodium Chloride Injection, USP, and about 6 to 8% in 5% Dextrose Injection, USP. Unacceptable losses occurred at 24 hours. A precipitate has also been noted during this time interval.

> **CAUTION**: The single-use lyophilized dosage form contains no antibacterial preservatives. Therefore, it is advised that the constituted product be discarded within 8 hours of initial entry.

Route of Administration: Intravenous